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10/548,748	09/08/2005	Markus Frank	12810-00137-US	1250
23416 7590 05/01/2007 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207			EXAMINER	
			IBRAHIM, MEDINA AHMED	
WILMINGTON, DE 19899			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

. The time period for reply, if any, is set in the attached communication.

Office Action Summary		Application No.	Applicant(s)		
		10/548,748	FRANK ET AL.		
		Examiner	Art Unit		
		Medina A. Ibrahim	1638		
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address		
VVHIC - Exter after - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONE	l. ely filed the mailing date of this communication.		
Status					
2a) <u></u> □	Responsive to communication(s) filed on 16 Ma This action is FINAL . 2b) This Since this application is in condition for allowan closed in accordance with the practice under Ex	action is non-final. nce except for formal matters, pro			
Dispositi	ion of Claims				
5)□ 6)⊠ 7)□	Claim(s) 1-21 is/are pending in the application. 4a) Of the above claim(s) 12 and 13 is/are without Claim(s) is/are allowed. Claim(s) 1-11 and 14-21 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or				
Applicati	on Papers				
9)⊠ 10)□	The specification is objected to by the Examiner The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the drawing sheet(s) including the correction to the order of the oath or declaration is objected to by the Example 1.	epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obje	37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
Priority u	ınder 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
2) 🔲 Notice 3) 🔯 Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4) Interview Summary (Paper No(s)/Mail Dat 5) Notice of Informal Pa 6) Other:	e		

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and SEQ ID NO: 1 in the reply filed on 03/16/07 is acknowledged. The traversal is on the ground(s) that the common technical feature shared by all claims of Groups I and II is the BI1 proteins and not the mere fact that a polypeptide is encoded by a nucleotide sequence. Applicant argues that the claims of the instant application is similar to that of Example 39, in Chapter 10 (10.59), of the PCT International Search and Preliminary Examination Guidelines established by the International Bureau of WIPO for the determination of Unity of Invention, where the claims to a protein and its encoding DNA are to be considered together as having unity of invention, especially when the protein is not known in the art. Applicant, therefore, requests that the requirement be withdrawn and that all claims be considered in this application. This is not found persuasive because the technical feature common to both the inventions I and II, namely, Bax inhibitor I and its use in transgenic plants, are known in the prior art as evidenced by the art rejections below. Therefore, the Bax inhibitor I recited in the claims of Group I is not limited to the isolated Bax inhibitor proteins of claim 12 in Group II. In addition, the claims in this application are not analogous to the claims in Example 39 of the PCT International Search and Preliminary Examination Guidelines, because unlike the novel protein of claim 1 in the Example, the common technical feature that links Group I and Group II, Bax inhibitor I, is not novel. Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-21 are pending.

Claims 12-13 are withdrawn from consideration as being directed to the nonelected invention.

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Claims 1-11 and 14-21 are pending and are examined.

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR1.821 (a)(1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 as shown in the attached Notice to Comply. The sequence on page 49, lines 13-14 is not identified by SEQ ID NO: 1. Also, the sequences of Figures 1 and 6 are not identified by SEQ ID NO: in the description of Figures on pages 77-80. The 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Applicant is respectfully requested to identify the sequences on page 49 and on Figures 1 and 6 or to submit a new Sequence Listing, which comprises said sequences.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in

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upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (I) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is also objected to because of the following informalities: for example, page 49, line 29, contains an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser- executable code are not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to check the specification for embedded hyperlinks or other form of browser-executable code and delete them. See MPEP 608.01.

Copending Applications

Applicants must bring to the attention of the Examiner, or other Office official involved with the examination of a particular application, information within their

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knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc.* v. *Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

Claim Objections

Claims 5 and 21 are objected to for reciting non-elected sequences. The Claims should be amended accordingly.

At claim 5, part (b), "selection" is not a method step. It is suggested that "selection" be changed to ---selecting---.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 15 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite because the sources of the "MLO", "RacB", NaOx", "PEN2", "SNAP34" and "PEN1" are unclear. The method of claim 1 does not indicate that these proteins are either inherent in the plant or are encoded by transgenes, like the BI1 protein. Clarification is required to more clearly define the metes and bounds of the claims.

Claims 11 and 20 are indefinite in the recitation of "mlo resistant phenotype" which is not clearly defined in the specification. The phrase is open to individual

interpretations such as a plant having resistance induced by mlo gene or a plant having resistance a broad spectrum of biotic and abiotic resistance or a disease caused by *Blumeria graminea sp.hordei* or *Erysiphe graminis sp.hordei*. Therefore, the metes and bounds of the claims are unclear.

Claim 15 is indefinite because "BI1 protein as defined in claim 4" lacks antecedent basis in claim 4. Claim 4 is directed to a method rather than a protein. Also, "The recombinant expression cassette" lacks antecedent basis.

Claim 21 is indefinite because "BI1 protein as defined in claim 5" lacks antecedent basis in claim 5. Claim 5 is directed to a method rather than a protein. Also, "The recombinant expression cassette" lacks antecedent basis.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 14-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of generating resistance in a plant to at least one plant pathogen by transforming the plant with an isolated nucleic acid encoding an unmodified Bax protein under the control of a desired promoter, and a recombinant vector/cassette comprising said nucleic acid, does not reasonably provide enablement for other methods of increasing amount or function of a BI1 protein in plants or methods that employ sequence comprising a motif having at least 50% identity to

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SEQ ID NO: 45-54 or to SEQ ID NO:2 or a part thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

The claims are drawn to a method of generating or increasing resistance to at least one biotic or abiotic stress in a plant by increasing amount or function of at least one Bax inhibitor 1 protein in a plant tissue with the proviso that the expression of said protein in leaf epidermis remains unchanged or reduced. The claims are also drawn to said method, wherein said BI1 protein comprises at least one motif having at least 50% homology with BI1 consensus of SEQ ID NO: 45 to 54, or has 50% sequence identity to SEQ ID NO: 2 or a part thereof.

Applicant teaches isolated nucleic acid sequences encoding barley BII protein. Applicant also teaches alignment of BI-I protein sequences from plants (figures 1 and 6). Applicant further teaches that BI1 in barley is predominantly expressed in the mesophyll tissue of leaves and is upregulated by infection with *Blumeria graminea sp. Hordei* (Examples 2 and 6). Applicant further teaches methods of overexpressing barley BI1 protein in wheat, wild-type barley and mlo barley and evaluation of the development of the fungal pathogen after inoculating the leaves with Bgh. Applicant further teaches overexpression of BII that significantly increases the penetration frequency of Bgh; while overexpression in mlo resistant barley resulted in a complete reconstitution of the susceptible phenotype (Figures 10-13).

Applicant, however, has not taught methods other than transformation of plants with BI1 nucleic acid expressed under the control of a desired promoter. Applicant has

not provided guidance for other methods of increasing BI1 protein amount or function in plants that resulted in increased resistance against exemplified or non-exemplified stress factors. Neither the specification nor the prior art teaches which part or which ten amino acids is responsible for the BI1 function. Applicant has not taught a single variant of the disclosed BI1 sequences having both the structure (% of sequence identity/homolog; fragment/part) and the desired function that can be used in the claimed methods.

The breadth of the claims encompasses sequences obtainable by multiple of modifications including multiple substitutions and/or deletions of nucleotides/amino acids in BI1 sequences. However, neither the prior art nor the instant specifications has taught which regions in a BI1 sequence would tolerate such modifications. Therefore, Applicant has not provided guidance for modifications to SEQ ID NO: 2 that resulted in nucleotide sequences having both the structural and functional limitations as recited in the claim.

While mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims. One skilled in the art would expect any tolerance to modification for a given DNA/protein to diminish with each further and additional modification or multiple substitutions/ deletions. One skilled in the art would have to make all possible amino acid substitutions and deletions in the 247 sequence of SEQ ID NO: 2 and test all amino acid sequences that meets the structural limitations to determine which also meet the functional limitation.

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Furthermore, Applicant has not provided guidance for a method of increasing resistance to all biotic and abiotic stresses including resistance to nematodes, virus, aphids, cold, heat, drought and other environmental stress conditions using BI1 protein or the obtention and use of the BI1 sequences as broadly claimed or methods of their use in organisms other than plant and microbial organisms. The specification is completely silent with respect to how to use BI1 sequences in human/animals to increase resistance to all abiotic and biotic stresses as claimed 17-18.

The state of the prior art teaches unpredictability inherent in DNA/protein function if one or more amino acids/bases in that DNA/protein are modified. For example, Broun et al (Science, 13 November 1998, vol. 282, pp. 1315-1317 (V)) teach that as few as four amino acid substitutions in a protein can change the protein activity (Abstract). Note, the proteins (mutated and original) disclosed by Broun would share more than 50% sequence identity. Therefore, it is unpredictable if any BI1 sequence having at least 50% identity/homology to SEQ ID NO: 2 or part thereof would retain the desired function.

The state of the prior art is that the mechanism of programmed cell death in plants is complex and not well understood and that transforming a plant with a BI1 inhibitor gene to increase resistance is unpredictable. For example, Mittler et al (Plant Cell (1996) 8:1991-2001) teach expression of a BaxI1 gene in transgenic plants that didn't result in resistance to bacterial and viral induced cell death (see at least Abstract on page 19991, and Discussion pages 1996-1998).

The state of the prior art for transforming a plant to induce a universal resistance

is unpredictable. For example, Ryals et al (The Plant Cell (1996), vol. 8, pp. 1809-1819) teach tobacco plants expressing SAR gene to induce broad spectrum of disease resistance that does not produce the expected resistance. Ryals et al state " in tobacco SAR activation results in a significant reduction of disease symptoms caused by the fungi *Phytophthora parasitica*, *Cercospora nicotiana*, and *peronspora tabacina*, the virus tobacco mosaic virus (TMV) and tobacco necrosis virus....... However, the protection is not effective against all pathogens". For example, there is no significant protection against either *Botrytis cinerea or alternaria alternata*".

The state of the art for isolating genes with specified function is highly unpredictable. Substantial guidance is required with respect to hybridization/wash conditions that would allow the specific isolation of the target genes. In the absence of such guidance, one skilled in the art has to proceed with trial and error experimentation to screen through the vast number of cDNA and genomic clones to identify those genes and variants/fragments thereof capable of reducing amount/activity/function of a BI1 protein in a plant cell, and to evaluate the ability of said genes to increase plant disease resistance against iron deficiency in any organism.

Therefore, given the lack of guidance in the specification and in the prior art; the unpredictability inherent in gene function and sequence modifications; and the nature of the invention as discussed above, the claimed invention cannot be practiced throughout the broad scope, therefore, the invention is not enabled. See, In re Wands 858 F.2d 731, 8USPQ2nd 1400 (Fed. Cir.1988). See also, *In re Fischer, 166 USPQ 19 24*

(CCPA 1970) where the court determined that the scope of the claims must bear a reasonable correlation with the scope of the enablement.

Written Description Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 14-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a multitude of recombinant vectors comprising a multitude of sequences, fragments and variants of BI1 proteins that are described by function only, i.e., their ability to increase resistance upon expression in a plant and methods that employ said sequences. In contrast, Applicant describes a recombinant vector comprising nucleic acids encoding SEQ ID NO: 2 from barley and methods that employ said nucleic acids. These are genus claims.

In Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997), the court stated:

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention... Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404).

The court held that held that human insulin-encoding cDNA is not described by

prophetic example, which sets forth only a general method for obtaining the human cDNA:

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity...Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes...does not necessarily describe the DNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA....Accordingly, the specification does not provide a written description of human cDNA (43 USPQ2d at 1405).

The description of a single species of rat cDNA was held insufficient to describe the broad genera of vertebrate or mammalian insulin:

"In claims to genetic material...a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It doesn't define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function...does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (43 USPQ2d at 1406).

The court continued:

"Thus...a cDNA is not defined by the mere name 'cDNA', even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA...A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". (43 USPQ2d at 1406). See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicant has not described the composition and structure of all BI1 protein sequences comprising at least one motif having at least 50% homology with BI1

consensus of SEQ ID NO: 45 to 54, or has 50% sequence identity to SEQ ID NO: 2. A substantial variation in structures and function are expected among sequences having 10 contiguous amino acids of SEQ ID NO: 2 in common, and among sequences with at least one motif having at least 50% homology with SEQ ID NO: 45 to 54. The motif sequences of SEQ ID NO: 45-54 each is only from 6-10 amino acids long. Since the BI1 sequences are not adequately described methods, recombinant vectors and plants comprising said sequences are similarly not described.

Therefore, for all the reasons discussed above, the claimed invention does not meet the current written description requirements. See, also, the Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14, and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Flinn et al (US 6, 451,604 A1).

The claims are drawn to a recombinant expression cassette/vector comprising a nucleic acid sequence encoding a BI1 protein operably linked to a heterologous tissue-specific promoter, said BI1 protein comprising a motif having at least 50% identity to SEQ ID NO: 45-54 or 50% identical to SEQ ID NO: 2 or a part thereof comprising at least 10 contiguous bases, said promoter having essentially no activity in the leaf epidermis, said promoter is mesophyll, root or tuber -specific promoter; and a recombinant plant comprising said expression cassette/vector. The claims are also drawn to said recombinant plant additionally having an mlo resistant phenotype.

Flinn et al teach a recombinant vector comprising a nucleic acid encoding a plant Bax inhibitor I (BI1) protein operably linked to a heterologous promoter; said promoter include inducible, constitutive or tissue specific, and transgenic tobacco plants

expressing said BI1 protein. The nucleic acid encoding tomato Bax inhibitor I (BI1) protein comprises at least one motifs SEQ ID NO: 45-54 and a part of Applicant's SEQ ID NO: 2 and has more than 50% identity thereto. Also, transgenic plants expressing BI1 protein inherently has mlo resistant phenotype. Therefore, Reed teaches all claim limitations.

Claims 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Reed, John (US 20030009785 A1).

Reed teaches a recombinant expression vector comprising a nucleic acid encoding tomato Bax inhibitor I (BI1) protein operably linked to a heterologous promoter; said promoter include inducible, constitutive or root specific, and transgenic plants expressing said BI1 protein; said plants include rice, corn, wheat, soybean, common fruits, and turf grass. The cited reference also teaches seed or a fruit tissue derived from said transgenic plant and expressing said tomato BI-1 polypeptide. The nucleic acid encoding tomato Bax inhibitor I (BI1) protein comprises at least one motifs SEQ ID NO: 45-54 and a part of Applicant's SEQ ID NO: 2. Also, transgenic plants expressing BI1 protein inherently has mlo resistant phenotype. Therefore, Reed teaches all claim limitations.

Remarks

Claims 1-11 are free of the prior art of record.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/20/07 Mai

MEDINA A IBRAHIM
PRIMARY EXAMINER A JON